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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,015	02/17/2004	Guy Bemis	V2018-700110	2429
37462	7590	05/29/2009		
LANDO & ANASTASI, LLP ONE MAIN STREET, SUITE 1100 CAMBRIDGE, MA 02142			EXAMINER ZHOU, SHUBO	
			ART UNIT 1631	PAPER NUMBER
			NOTIFICATION DATE 05/29/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/781,015	Applicant(s) BEMIS ET AL.	
	Examiner SHUBO (Joe) ZHOU	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 34 is/are rejected.
- 7) ☒ Claim(s) 1-31 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendments filed 2/9/09 are acknowledged and entered.

Claims 1-34 are currently pending, and claims 1-31 and 34 are under examination. Claims 32-33 have been previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Drawings

The amended drawings filed 2/9/09 is acknowledged and accepted.

Specification

The objection to the specification set forth in the previous Office action mailed 3/22/07 has been withdrawn in view of the amendment to the specification filed 2/9/09.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-31 and 34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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Note that the rejection with regard to the method claims is reiterated from the previous Office action with modification in view of recent court decisions including *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008).

Claims 1-28 and 34 are drawn to a method or apparatus comprising computer programs for executing the process, the process comprising: a) providing a structural model of a query ligand and a structural model of a target macromolecule; b) identifying a substructure of the query ligand; c) identifying comparison ligands in a set of 3-D structural models that each share an identical substructure with the query ligand, wherein each 3-D structural model comprises a comparison ligand and a comparison macromolecule, and wherein the comparison macromolecule has structural features homologous to the target macromolecule; d) mapping spatial relationships between the substructure atoms of the query ligand and the comparison ligand such that corresponding atoms are identified; e) assigning atomic coordinates to the corresponding atoms of the query ligand; f) generating one or more output models, each model comprising a 3-D structural model of the query ligand substructure and the target macromolecule, wherein the 3-D model of the query ligand substructure comprises the atomic coordinates of the query ligand from step (e).

The Supreme Court has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed process is patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See *Benson*, 409 U.S. at 70 ; *Diehr*, 450 U.S. at 192 ; see also *Flook*, 437 U.S. at 589 n.9 ; *Cochrane v. Deener*, 94 U.S.

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780, 788 (1876). The same test is emphasized in *In re Bilski* as the only test for determining whether a claimed method is a statutory process. *Id.*

In the instant case, the claims only in the preamble refer to "computer-based method." Given that the method is claimed as "comprising" the recited method steps, even though the method is computer-based, it does not mean the recited steps are computer-based. Furthermore, there is no detailing as to the particulars of a computer in relation to the claimed method steps. Thus, the claimed method is not deemed to be tied to a particular machine or apparatus. Moreover, there is no physical transformation because a process of mathematical modeling does not transform an article or physical subject to a different state or thing. Therefore, at least one embodiment of the claimed method is not a statutory process. In addition, the court has pointed out that the involvement of the particular machine/apparatus or transformation in a claimed process must not merely be insignificant extra-solution activity. See *Flook*, 437 U.S. at 590. In the instant case, the association with a device is only casually mentioned in the preamble, which in this case falls into the insignificant extra-solution activity.

With regard to claims 30 and 31 drawn to apparatus or an article comprising computer readable medium, even though the claims are amended to "display" the generated model, it is not clear how it is displayed and whether the displayed model is accessible to a user. Thus, at least one embodiment of the invention does not produce a tangible result.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 and 34 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following rejection under 112, second paragraph, is reiterated from the previous Office action. Those set forth in the previous Office action but not reiterated below are withdrawn in view of applicant's amendment to the claims filed 2/9/09.

Step (c) of claim 1 recites a "comparison macromolecule has structural features homologous to the target macromolecule." The term "homologous" is a relative term that renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. When the 3-D structures of two molecules are compared, some part of the molecules might share the same atoms at corresponding positions, and some different atoms might share the same spatial shape or form. Without an explicit standard or criteria for determining whether two structures are homologous, it would not be clear to one skilled in the art what structures are homologous and what are not.

In the response filed 2/9/09, applicant argues that the specification provide examples and exemplary characteristics for homologous macromolecules include

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sequence relatedness, three-dimensional relatedness, etc. See page 14 of the response.

This is not found persuasive because the problem is not that there is no example, but rather there is no guidance as to the standards for homologousness. For example, if sequence relatedness is one characteristic for being homologous, one skilled in the art would not be clear how much relatedness between two sequences is considered as being homologous. A 90% identity between two sequences will probably be considered as homologous, but how about 30%, 20% or even 5%?

Claim 9 recites the phrase “the cyclic portions,” which lacks clear antecedent basis because there is prior reference to cyclic portions, and it is thus unclear what they are.

In the response filed 2/9/09, applicant states that the claim has been amended to provide antecedent basis for the phrase “the cyclic portions,” but there is no amendment noticed for the claim in the amendment filed 2/9/09, and the status of the claim provided is “original.”

The phrase “the compound” recited in claim 34, line 7, i.e. in step (c), lacks adequate antecedent basis because there is prior reference to at least two compounds: a ligand and a target macromolecule. Thus it is unclear which one of the two compounds is meant in line 7.

It’s noted that in response to the previous Office action, claim 34 is amended such that only the word “compound” recited in step (b) is changed to “ligand.”

Clarification of the metes and bounds of the claims is requested.

Claim Objections

Claims 1-31 and 34 are objected to because of the following reasons including informalities:

The phrase recited in step (c) of claim 1, “identifying comparison ligands in a set of 3-D structural models that each share an identical substructure with the query ligand ...” is grammatically awkward. Is the word “so” missing in between the words “models” and “that?” It also appears that the singular tense of share, i.e. “shares” would be grammatically proper.

Appropriate correction is required.

In the response filed 2/9/09, applicant did not respond to the above claim objection.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center

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/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER